

PTO/SB/21 (08-03)

Approved for use through 08/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Application Number 10/705,996

Filing Date 11/13/03

First Named Inventor, *d* Platteeuw

Art Unit 1615

Examiner Name Unassigned

Total Number of Pages in This Submission

197

Attorney Docket Number SYN-0053

ENCLOSURES (Check all that apply)

- | | | |
|--|---|---|
| <input type="checkbox"/> Fee Transmittal Form | <input type="checkbox"/> Drawing(s) | <input type="checkbox"/> After Allowance communication to Technology Center (TC) |
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| <input type="checkbox"/> Amendment/Reply | <input type="checkbox"/> Petition | <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) |
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| <input checked="" type="checkbox"/> Information Disclosure Statement | <input type="checkbox"/> CD, Number of CD(s) _____ | |
| <input type="checkbox"/> Certified Copy of Priority Document(s) | Remarks | |
| <input type="checkbox"/> Response to Missing Parts/Incomplete Application | | |
| <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | | |

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENTFirm
or
Individual nameMark R. Buscher
Reg. No. 35,006

Signature

Date

8/18/2004

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name

Mark R. Buscher

Signature

Date

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	
Johannes J. PLATTEEUW.	:	Examiner: Unassigned
Serial No. 10/705,996	:	Group Art Unit: 1615
Filed: Nov. 13, 2003	:	Docket No.: SYN-0053
For: Pharmaceutical Pellets Comprising Tamsulosin	:	

INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents and Trademarks
P.O. Box 1450
Alexandria, VA 22313-1450

August 18, 2004

Sir:

Applicants hereby submit a copy of each document, except the US Patents and US Published Applications, listed on the attached PTO-1449 Form, for entry into the above-identified application and consideration by the Examiner.

This Information Disclosure Statement is being submitted before a first Office Action on the merits under 37 C.F.R. § 1.97(b), and thus no fee is due.

This Statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the documents submitted herewith.

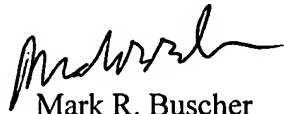
Having complied with rules 97 and 98, applicants request that the listed documents be officially considered by the Examiner, that the Examiner initial and return a copy of the 1449

Serial No. 10/705,996

Form, and that the listed documents be printed among the "References Cited" on any patent to issue from this application.

Should the Examiner have any questions regarding this application, the Examiner is requested to contact applicants' representative, Mark R. Buscher (Reg. No. 35,006) at telephone number 703 753 5256.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mark R. Buscher', written in a cursive style.

Mark R. Buscher
Registration No. 35,006

P.O. Box 161
Catharpin, VA 20143
703 753 5256

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	3
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PTO/SB/08A (08-03)

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information unless it contains a valid OMB control number.

Complete if Known

Application Number	10/705,996
Filing Date	11/13/2003
First Named Inventor	Platteeuw
Art Unit	
Examiner Name	
Attorney Docket Number	SYN-0053

U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

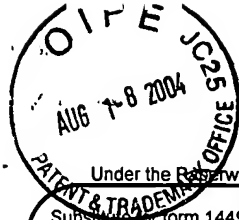
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		EP 0 034 432 B1	02-02-81	Imai et al.		
		EP 0 194 838 B1	09-06-93	Fukui et al		
		EP 0 533 297	11-19-97	Fukui et al.		

Examiner Signature		Date Considered	
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number 10/705,996

Filing Date 11/13/2003

First Named Inventor Platteeuw

Art Unit

Examiner Name

Attorney Docket Number SYN-0053

Sheet 2

of 3

NON PATENT LITERATURE DOCUMENTS

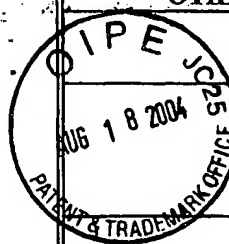
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		NDA 20-579, FDA Office of Clinical Pharmacology and Biopharmaceutics Review, pp 1-6, 1997	
		Flowmax, MIMMS Abbreviated Prescribing Information, MIMMS Australia, 1996-2002	

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OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)

	Presentation entitled: "In Vivo Performance of Hydrophilic Matrix Tablets Utilizing HPMC: Case Studies" by Tim D. Cabelka, Ph.D. and Thomas D. Reynolds, Ph.D. , The Dow Chemical Company, October 17, 2000.
	FDA - FOIA Labeling Information for Flomax®, 2001
	Dunn CJ, Matheson A and Faulds DM. "Tamsulosin A review of its pharmacology and therapeutic efficacy in the management of lower urinary tract symptoms." <i>Drugs Aging</i> 2002; 19; 135-161.
	Dutkiewics S. "Efficacy and tolerability of drugs for treatment of benign prostatic hyperphasia." <i>Int Urology and Nephrology</i> 2001; 32; 423-432
	Harada K. and Fujimara A. " Clinical pharmacology of α_1 selective and nonselective β -blockers." <i>BJU International</i> 2000; 86; 31-35
	Lyseng-Williamson KA, Jarvis B and Wagstaff AJ. "Tamsulosin An update of its role in the management of lower urinary tract symptoms." <i>Drugs</i> 2002; 62; 135-167
	Michel MC, Neumann HG, Mehlburger L, Schumacher H and Goepel M. "Does the time for administration (morning or evening) affect the tolerability or efficacy of tamsulosin ?" <i>BJU International</i> 2001; 87; 31-34
	Soeishi Y, Korobi M, Kobayashi SI and Higuchi S. " Sensitive method for the determination of amsulosin in human plasma using high-performance liquid chromatography with fluorescence detection" <i>J of Chromatography</i> 1990; 553: 291-296
	Taguchi K, Schafers RF and Michel MC. "Radioreceptor assay analysis of tamsulosin and terazosin pharmacokinetics." <i>Br J Clin Pharmacol</i> 1998; 45: 49-55
	van Hoogdalem EJ, Soeishi Y, Matsushima H and Higuchi S. "Disposition of the selective α_1 adrenoceptor antagonist tamsulosin in humans: Comparison with data from interspecies scaling." <i>J Pharm Sciences</i> 1997; 86: 1156-1161.
EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.